

## REMARKS

In the Office action dated June 16, 2009, claims 1-3, 8, 9, 12, 13, 28-31 and 37 were provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-13 of co-pending application 10/549,211. Claims 1-3, 8, 9, 12, 13 and 28-36 were rejected under 35 U.S.C. § 112, second paragraph. Claims 1-3, 8, 9, 28, 29, 32, 33 and 37 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,896,007 to Cymbalisty. Claims 1-3, 8, 9, 12, 28-30, 32-34, 37 and 38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,039,754 to Caro, in view of Cymbalisty. Claims 13 and 31 were rejected as being unpatentable over Caro and Cymbalisty in further view of U.S. Patent No. 5,670,161 to Healy et al. (Healy). Claims 35, 36, 39 and 40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro and Cymbalisty in further view of British Patent No. 2 298 577 to Angelini. For the reasons outlined in detail below, it is respectfully submitted that the pending claims are in condition for allowance over the art of record.

### Double Patenting

In paragraph 4 of the Office Action, it was noted that certain of the pending claims of the instant application, namely, claims 1-3, 8, 9, 12, 13 and 28-36, were provisionally rejected over claims 1-13 of co-pending application Serial No. 10/549,211. This is only a provisional obviousness-type double patenting rejection, because the conflicting claims have not yet been patented. Applicant defers a substantive response to this provisional rejection until such time as the conflicting claims are patented. At that point, if it is called for, a terminal disclaimer will be filed.

### § 112 Rejections

Section 6 of the Office Action set forth a number of indefiniteness rejections pertaining to claims 1-3, 8, 9, 12, 13 and 28-36. It is believed that applicant has rectified all of these issues with the enclosed set of claims. Therefore, these rejections are now believed to be moot.

### Cymbalisty - Claims 1-3, 8, 9, 28, 29, 32, 33 and 37

Independent claims 1, 3 and 37 were rejected as being anticipated by

Cymbalisty. In this connection, it was asserted that Cymbalisty discloses a graft (considered to be a tube) comprising flow tubing having a tubing portion defining a substantially circular flow lumen wherein the graft is set such that the center line of the flow lumen follows a substantially helical path. Figure 2 was identified in this regard. Paragraph 6 of the Office Action contended that Cymbalisty shows a helix angle less than or equal to 15 degrees. Figure 3 was identified in this regard. It was also asserted that the amplitude of the helical center line is less than or equal to one half of the internal diameter of the tubing portion and wherein the amplitude of the helical center line divided by the internal diameter of the tubing portion is at least 0.05.

Independent claim 1 has been amended to clearly recite a graft for biomedical use, the graft comprising flow tubing which is for use in vivo to carry blood or other bodily fluids and which is made of a biocompatible material. In this connection, applicant notes that the instant application explicitly mentions the biomedical applications of the graft at page 10, line 36 to page 11, line 7. It is there stated that the graft can be employed for various biomedical applications, both for blood and other bodily fluids in various arteries, veins, as well as non-cardiovascular applications. Basis for defining the flow tubing as being used in vivo can be found in the instant application at page 4, lines 14-15, as well as on page 12, at lines 12-14. As to the flow tubing being made of a biocompatible material, the Examiner's attention is directed to the instant specification at page 14, line 34, as well as at page 21, lines 16-19.

In contrast to the claimed invention, Cymbalisty pertains to a static mixing apparatus for flowing fluidized slurries of sand, oil and water, such as would be used in separating oil sands. This is clearly evident from the specification and drawings of Cymbalisty, particularly Figure 6 thereof.

Cymbalisty is non-analogous art. A person skilled in the art of grafts for use in vivo would not resort to examining patents dealing with heavy duty pipes for oil sand slurries when looking for useful teachings. There are a multitude of differences between the claimed in vivo graft and the Cymbalisty industrial pipe. First, the graft is employed for a medical prosthesis and the pipe is used in heavy industry. Second, the materials carried by the graft (i.e., blood or other bodily fluids) and by the pipe (i.e., oil, sand and water slurries with a very high sand content) are completely different. Third, the

diameters of the graft and the pipe are different by at least one order of magnitude, if not several.

Fourth, the materials from which the claimed graft, on the one hand, and the Cymbalistry pipe, on the other hand, are made are completely different. The graft is made from a biocompatible material. In contrast, the Cymbalistry pipe is made from industrial concrete or steel. Fifth, in vascular applications of the claimed graft, the flow is a pulsating flow, based on the pumping of the heart (see for example the paragraph bridging pages 6 and 7 of the instant application). In contrast, the flow in Cymbalistry is a steady or continuous flow. For example, the hydro mixer B shown in Figure 6 of Cymbalistry carries a slurry through a mixer (column 6, lines 55-58 of Cymbalistry). The hydro mixer E of Figure 6 in Cymbalistry carries the slurry, which is shown to flow under gravity (see column 7, lines 30-34 of Cymbalistry).

Because Cymbalistry is non-analogous art, claim 1 is not anticipated by Cymbalistry. Rather, claim 1 clearly patentably defines over Cymbalistry. Dependent claims 2, 8, 9 and 32 also patentably define over Cymbalistry.

Similarly, independent claim 3, which was asserted to be anticipated by Cymbalistry, and which also recites a graft for biomedical use in vivo to carry blood or other bodily fluids and which is made of a biocompatible material, patentably defines over Cymbalistry. So, too, do its dependent claims 28, 29 and 33.

Independent claim 37 was also rejected as being anticipated by Cymbalistry. Claim 37 similarly recites a graft for in vivo use comprising a flow tubing to carry blood or other bodily fluids and which tubing is made of a biocompatible material. For the reasons advanced above, independent claim 37 also patentably defines over Cymbalistry.

#### Caro and Cymbalistry - Claims 1-3, 8, 9, 12, 28-30, 32-34, 37 and 38

Claims 1, 2, 8, 9, 12, 32 and 34 were rejected as being unpatentable over the combination of Caro and Cymbalistry. In this connection, it was stated that Caro discloses a graft comprising flow tubing having a tubing portion defining a flow lumen, with the flow lumen being substantially free of ribs or grooves, wherein the graft is set such that the center of the flow lumen follows a substantially helical path. It was

admitted that Caro does not disclose that the center line of the flow lumen has a helix angle of less than or equal to 45 degrees and that the amplitude of the helix is less than or equal to one half of the internal diameter of the tubing, wherein the amplitude of the helical center line divided by the internal diameter of the tubing is at least 5 percent. Cymbalistry was said to be employed for providing those teachings which are missing from Caro. It was asserted that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the helical formation of the graft shown in Caro in view of the specific dimensions taught by Cymbalistry in order to provide flow tubing which creates swirl flow and prevents blockages with the interior of the graft. It was asserted that the open channel shown in Cymbalistry is effective to provide a conduit for blood even if blockages do form along the tubing walls. This rejection is respectfully traversed.

As noted above, Cymbalistry is non-analogous prior art. What a person of ordinary skill in the art would learn from Cymbalistry is that the reference does not provide any advantages relating to grafts of the type disclosed in Caro. The reason for this is that the Cymbalistry pipe is employed for carrying mined oil sands, which are a mixture of coarse sand particles coated by a thin film of water, with oil filling the interstices, and minute particles of clay and minerals distributed within the water sheaths (see column 1, lines 44-47 of Cymbalistry). Cymbalistry states that his pipe is particularly employed for mixing multiple phase mixtures of sand, oil and water, i.e., slurries of same (see column 2, lines 7-11). Cymbalistry notes that the solids carried in his pipe are abrasive (column 2, lines 22-26) and his pipe construction dissipates the abrasive action of the solids.

It was asserted in the Office Action that the Cymbalistry conduit "prevents blockages" and it was further asserted that the open channel shown in Cymbalistry is effective to provide a conduit for blood even if blockages do form along the tubing walls. Because Cymbalistry deals with slurries of sand, oil and water, the main objective in Cymbalistry is to keep the water/oil/sand slurry well mixed, thereby keeping the elements in suspension. Keeping the elements in suspension minimizes the abrasive effects of the high volume of solids on the wall of the pipe (see column 2, lines 7-32 of Cymbalistry in this regard).

Hyperplasia is an inflammatory response of living tissue and the inflammation can occur anywhere around the wall of the vessel. There is no particular concern with build up at the bottom of the vessel as is the case with Cymbalistry.

It is also stated in the instant application that the non-planar curvature of the graft improves "circulation by rendering the distribution of wall shear stress relatively uniform and suppressing flow separation and flow instability, and as a result, inhibiting the development of vessel pathology." See the instant specification at page 21, lines 8-16. The more uniform distribution of wall shear stress achieved by the claimed graft is thus considered beneficial in a biological sense. Cymbalistry does not even recognize the advantage of relatively uniform distribution of wall shear stress, much less does it discuss or suggest the benefits to be achieved thereby.

The claimed invention seeks to prevent pathology in the natural vessel to which the graft is joined. Of course, there is no hint of these benefits in Cymbalistry. Thus, the skilled person in the art would have no reason to expect that the Cymbalistry geometry would be of any benefit for use in grafts.

The claimed invention further recognizes the advantages of swirl flow in the context of pulsating flow which occurs in vivo grafts. Such pulsing flow does not occur in Cymbalistry which pertains to the industrial sphere as noted above. It is stated on page 7, lines 4-9 of the instant specification that "even if there are stagnant flow regions at lower Reynolds numbers....these will tend to be flushed out during period of flow when the Reynolds numbers are higher." This flushing out effect is not recognized or even hinted at by Cymbalistry because Cymbalistry is not concerned with pulsating flows.

Moreover, the dynamic velocity vectors for flows resulting from a pressure pulse are significantly radial in the vascular application and will in fact propel the suspended blood particles towards the graft wall. If translated to the Cymbalistry pipe carrying slurry, this would lead to an increase in abrasion, which is something Cymbalistry seeks to avoid.

While the prevention of blockages may be an issue for sands/oil/water slurries, as in Cymbalistry, where sediment deposition occurs due to gravitation, there is no such concern in grafts which convey blood or other bodily fluid flows. In grafts, any deposit build up does not arise because of solid settlement. Although blood and other bodily

fluids may contain different components, such as plasma and platelets, these have similar densities. In an in vivo environment, there are no blockages due to gravity-caused settlement of solids. In sum, the mixing sought by Cymbalistry is to help with transport of dense solids along the pipe and prevent plugging. However, this is simply not an issue in an in vivo graft of the type recited in pending claim 1.

Not only is Cymbalistry non-analogous art, but the solution taught by Cymbalistry for gravity caused settlement is irrelevant for the in vivo environment of the graft claimed in the instant application. Therefore, it is respectfully submitted that independent claim 1 patentably defines over the asserted combination of Caro and Cymbalistry, as well as the remainder of the prior art.

Dependent claims 2, 8, 9, 12, 32 and 34, which merely further patentably define the detailed subject matter of their parent claim, are also in condition for allowance over the asserted combination, as well as the remainder of the cited art.

Independent claim 3 is similarly limited to a graft for biomedical use comprising a flow tubing which is for use in vivo to carry blood or other bodily fluids. Therefore, the arguments made above in connection with the patentability of independent claim 1 over the asserted combination of Caro and Cymbalistry also pertain to independent claim 3. So, too, do they pertain to dependent claims 28, 29 and 33. Therefore, it is respectfully submitted that claims 3, 28, 29 and 33 patentably define over the asserted combination of Caro and Cymbalistry, as well as the remainder of the cited art.

Independent claim 37 similarly recites a graft for in vivo use comprising flow tubing to carry blood or other bodily fluids. As a result, this claim is also believed to be in condition for allowance over the asserted combination of Caro and Cymbalistry, as well as the remainder of the cited art. Dependent claim 38 which merely further patentably defines the detailed subject matter of its parent claim is also believed to be in condition for allowance over the asserted combination of Caro and Cymbalistry, as well as the remainder of the cited art.

#### Caro, Cymbalistry and Healy - Claims 13 and 31

Claims 13 and 31 were rejected as being unpatentable over the three-way combination of Caro, Cymbalistry and Healy. Caro, in view of Cymbalistry was said to

disclose the invention substantially as claimed, but does not disclose a graft comprising a pharmaceutical coating. Healy was said to disclose a stent graft comprising a drug coating for the purpose of positively affecting healing at the site of implantation. It was then asserted that it would have been obvious to one of ordinary skill in the art at the time of the invention to add a pharmaceutical coating to the graft of Caro in view of Cymbalisty in order to induce healing at the site of implantation as taught by Healy.

However, in view of the fact that Cymbalisty is not analogous art, it would not have been obvious to combine Cymbalisty with Caro. Healy does not cure this deficiency in the proposed combination. Therefore, it is respectfully submitted that dependent claims 13 and 31 are patentable over the asserted three-way combination, as well as the remainder of the cited art.

#### Caro, Cymbalisty and Angelini - Claims 35, 36, 39 and 40

Claims 35, 36, 39 and 40 were rejected as being unpatentable over Caro in view of Cymbalisty and in further view of Angelini. Caro in view of Cymbalisty was said to disclose the invention substantially as claimed, but does not specifically disclose that the external support (which assertedly is taught in Caro) may be in the form of a helical winding where the helix angle of the helical winding is larger than the helix angle of the helical center line of the flow lumen. Angelini was said to teach a graft in the same field of endeavor wherein a stent with a large helical angle is used around a graft for the purpose of providing beneficial effects on luminal size, the degree of medial and intimal thickening, and cell proliferation. Page 2, lines 11-15 of Angelini were specifically noted. It was then asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the graft of Caro in view of Cymbalisty and to include the external helical winding taught by Angelini in order to help maintain the circular cross section of the tubing. Finally, it was noted that because Angelini discloses a helix angle of the helical winding to be close to 90 degrees, the helix angle of the helical winding is larger than the helix angle of the helical center line of the flow lumen of the device as modified.

However, as noted above, Cymbalisty is not analogous prior art. Therefore, the proposed combination of Caro, Cymbalisty and Angelini is untenable.

The skilled person in the art would have no reason to refer to Cymbalisty as that

patent pertains to a field of endeavor far removed from the in vivo grafts taught by Caro, as well as by Angelini. If the intention is to seek to prevent pathology in a natural vessel in vivo, to which the graft recited in the claims is joined, then, there is no hint of these benefits in Cymbalisty. There would be no reason to expect that the Cymbalisty geometry would provide benefits for use in grafts in vivo. Quite simply, Cymbalisty is non-analogous art and the person of average skill in the art would not have wished or even contemplated to combine Cymbalisty with either Caro or Angelini. Accordingly, it is respectfully submitted that claims 35, 36, 39 and 40 patentably define over the asserted combination of Caro, Cymbalisty and Angelini, as well as the remainder of the cited art.

#### Summary

In view of the amendments to the claims and the remarks advanced above, it is respectfully submitted that all of the pending claims are in condition for allowance over the applied references, in any combination, as well as the remainder of the cited art. Allowance of the pending claims is therefore earnestly solicited.

Respectfully submitted,

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